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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,464	03/01/2002	Athar H. Chishti	S01237/70019(ERP/MXA)	8902

7590 09/26/2003

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EXAMINER

MINNIFIELD, NITA M

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 09/26/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/087,464

Applicant(s)

CHISHTI ET AL.

Examiner

N. M. Minnifield

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 8, 15, 16, 18, 26-28, 31, 34, 35, 37, 38, 41, 42, 45-47 and 49 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 5 sheets
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7+10
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Continuation of Disposition of Claims: Claims withdrawn from consideration are 2,8,15,16,18,19,26-28,31,34,35,37,38,41,42 and 45-47.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 2,8,15,16,18,26-28,31,34,35,37,38,41,42,45-47 and 49.

DETAILED ACTION

Sequence Requirements

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Full compliance with the sequence rules is required in response to this office action. A complete response to this office action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with **both** the sequence requirements and Office action in the time period set forth in this Office action will be held non-responsive.

2. Applicant's election with traverse of Group I, claims 1, 18, 27, 37, 42 and 49 and species SEQ ID NO: 3, in Paper No. 9 is acknowledged. Applicants have respectfully requested examination of each of the polypeptide sequences set forth as SEQ ID NO: 1-4. Applicants have asserted that SEQ ID NO: 1-4 are regions of a single protein, with SEQ ID NO: 1-3 overlapping regions and SEQ ID NO: 4 an adjacent region of the same protein. Applicants submit that the search and examination of these sequences would not present an undue burden for the Examiner. It is noted that an examination of SEQ ID NO: 1-4 as it relates to claim 1 will be done in this application. All other restriction requirements have been maintained as previously set forth.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 2, 8, 15, 16, 18, 26-28, 31, 34, 35, 37, 38, 41, 45-47 and 49 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and/or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

4. Claim 1 and species, SEQ ID NO: 1-4 will be examined in this application.

5. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (for example see p. 51 of specification). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

6. The incorporation of essential material in the specification by reference to a particular GenBank accession number(s) is improper (see Tables 3 and 4 of the specification and the claims). Applicants are required to amend the disclosure to include the material incorporated by reference, such that the claims are precisely defined. The amendment must be accompanied by an affidavit or declaration executed by applicants, or a practitioner representing the applicants, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

7. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is vague and indefinite in the recitation of “unique fragments”; what does Applicant intend by “unique fragments”? The specification at page 20 indicates that unique fragments exclude fragments completely composed of the nucleotide sequences of any of GenBank accession numbers identified in Table 4 or other previously published sequences (see p. 20, l. 21 to p. 22, l. 2). The entire sequence of Band 3 polypeptide is known, therefore how can there be any “unique fragments” as defined by the specification? The meaning of this phrase is unclear. The claim is vague and indefinite in the recitation of “Table 4: Band 3 Blast Homology Sequences”. The table recites accession numbers, which may change over time and the metes and bounds of these Blast Homology Sequences, are not known.

8. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Band 3 polypeptide comprising an amino acid sequence of SEQ ID NO: 1-4, also referred to as B3_{5A}, B3_{5B}, B3_{5C} and B3_{6A} respectively, does not reasonably provide enablement for unique fragments of these sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification teaches the preparation of SEQ ID NO: 1-4. The specification teaches that Band 3 is host receptor binding MSP-1 in the malaria parasite *P. falciparum* invasion of RBC (example 5). Peptides 5B, 5C and 6A of Band 3 were most effective inhibitors

targeting *P. falciparum* invasion among all Band 3 peptides tested (see pp. 68-69). The specification indicates that Band 3 functions as an important receptor in parasite invasion in RBC. Example 5 also teaches that recombinant Band 3 peptides can be made 5ABC, 5AB and 6AB (see pp. 70-77). However, the specification does not teach how to make or use the unique fragments as recited in claim 1. Is the unique fragment something smaller than the amino acid sequences as set forth in SEQ ID NO: 1-4; is the unique fragment smaller 20 amino acids in size? What is the exact minimum size (number of amino acid) of the unique fragment such that the fragment will still function as SEQ ID NO: 1-4 (inhibiting targeting *P. falciparum* invasion)? The specification does not teach one skilled in the art any unique fragments of the claimed peptides.

Where is the “Supplemental material for Dataset 2: Description of genes b PlasmoDB”? This is recited in footnotes of Table 3 on p. 80 of the specification.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Lux et al 1989, Tanner et al 1988, Yannoukakos et al 1989, Kaul et al, 1983, Drickamer et al 1978, Brock et al 1983, Kawano et al 1988, Jennings et al 1992, Okubo et al 1991, Brunati et al 2000, Yannoukakos et al 1991, Jarolim et al 1991, Jarolim et al 1992, Schofield et al 1992, Bruce et al 1993, Rybicki et al 1993, Bruce et al 1994, Bruce et al 1995, Jarolim et al 1995, Maillet et al 1995, Jarolim et al 1996 or Eber et al

1996 (see Sequence Search Result Printout for SEQ ID NO: 1-4, SwissProt_41 Database).

Claim 1 is directed to an isolated Band 3 polypeptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 1-4 and unique fragments thereof, wherein the unique fragments bind to MSP-1 polypeptide and exclude the sequences set forth in Table 4: Band 3 Blast Homology.

The Sequence Search Result Printout list 22 different references that set forth the Band 3 polypeptide comprising the amino acid sequences as set forth in SEQ ID NO: 1-4 as presently claimed.

Since the Patent Office does not have the facilities for examining and comparing applicants' polypeptide with the polypeptide of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed polypeptide and the polypeptide of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

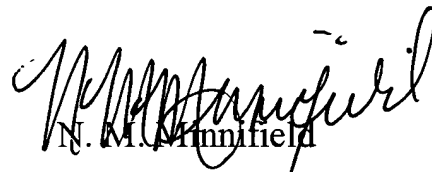
11. No claims are allowed.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'N. M. Minnifield', is written over the printed name.

N. M. Minnifield

Primary Examiner

Art Unit 1645

NMM

September 16, 2003